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## **FDA Modernization Act of 1997 (FDAMA)**

### **Section 406 (B):**

**Consult "with appropriate scientific and academic experts, health care professionals, representatives of patient and consumer advocacy groups and the regulated industry..."**

# **FDAMA Section 406 (b)**

## **Objectives:**

- **Maximize the availability and clarity of information about the process of review of applications and submissions**
- **Maximize the availability and clarity of information for consumers and patients concerning new products**

# **FDAMA Section 406 (b)**

## **Objectives:**

- **Implement inspection and postmarket monitoring provisions of the Act**
- **Ensure access to the scientific and technical expertise necessary to meet obligations**

# **FDAMA Section 406 (b)**

## **Objectives:**

- **Establish mechanisms for meeting established time periods for the review of all applications and submissions by July 1, 1999**
- **Eliminate backlogs in the review of applications and submissions by January 1, 2000**

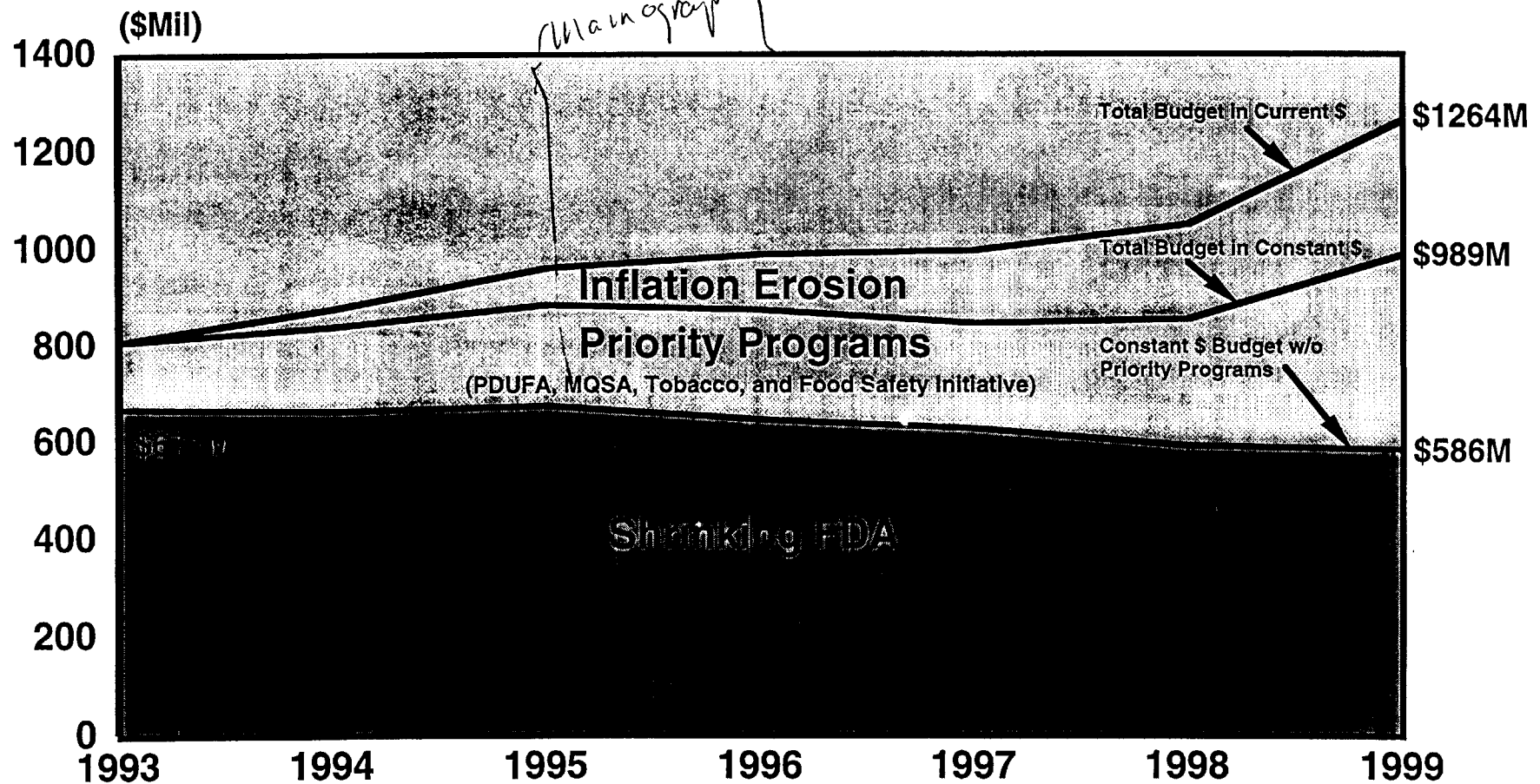
# **Issues of Concern**

- **Adverse Event/Injury Reporting**
- **Product Safety Assurance**
- **Product Application Reviews**

# Issues of Concern

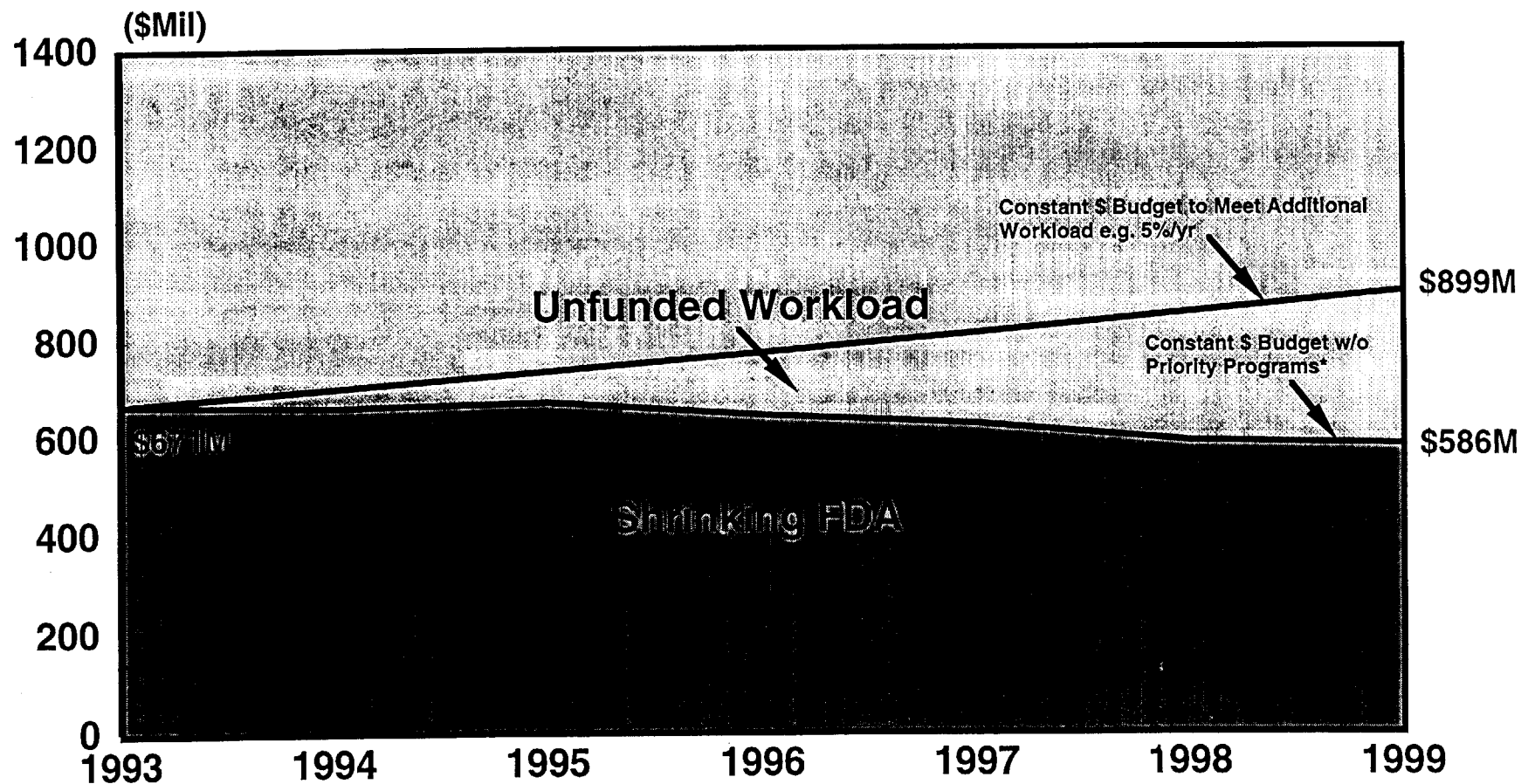
- **Food Safety**
- **Outreach**
- **Scientific infrastructure  
and research**
- **Tobacco**

# The Visible FDA



# The Shrinking FDA

(Constant Dollar Effort Relative to Increasing Workload)



\*Priority Programs = PDUFA, MQSA, Tobacco, and Food Safety Initiative.

Suydam/Grice, 8/98, AS



# FDA Modernization Act of 1997 (FDAMA)

Section 406 (b):

consult "with appropriate scientific and academic experts..."  
**Docket Number 98N-0339**  
of patient and consumer advocacy groups and the regulated industry..."

# **3 ways to comment**

## ***By mail:***

**Food and Drug Administration  
Dockets Management Branch  
Room 1061, HFA-305  
5630 Fishers Lane  
Rockville, Maryland 20852**

## ***Via email:***

**FDADOCKETS@BANGATE.FDA.GOV**

## ***Online:***

**<http://www.fda.gov/>**